REMARKS

Claims 13, 15, 36, 38, 59, 61, 82, and 84 have been cancelled without prejudice.

Claims 14, 37, 60, and 83 have been rewritten as independent claims and have been amended to remove the recitation of functional derivatives. Claims 14, 37, 60, and 83 have also been amended to further clarify the recitation of "stringent hybridizing conditions." Support for these amendments is found in original claims 14, 37, 60 and 83, respectively, and in the specification at, for example, page 3, lines 15-20, page 7, lines 29-34, and the Examples. *See In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01(o) and (l).

Claims 16, 39, 62, and 85 have been amended to depend from claims 14, 37, 60, and 83, respectively. Support for these amendments is found in original claims 16, 39, 62, and 85, respectively, and in the specification at, for example, page 3, lines 15-20. *See Id.*

The specification has been amended to provide a more descriptive title as suggested by the Examiner and now recites "Biotin Biosynthetic Genes Having KAPA Synthetase Activity." The specification has also been amended to clarify the high stringency conditions. Support for these amendments is found in original claims 14, 37, 60 and 83, respectively, and in the specification at, for example, page 7, lines 29-34, and the Examples. *See Id.*

It is submitted that no new matter has been introduced by the foregoing amendments. Approval and entry of the amendments respectfully is requested.

§112, Second Paragraph Rejection

Claims 13-16, 36-39, 59-62, and 82-85 were rejected under 35 U.S.C. §112, second paragraph. (Paper No. 20041117 at 2).

In making the rejection, the Examiner asserted that in claims 13, 36, 59, and 82 "the phrase 'functional derivatives thereof' renders each of the claims vague and indefinite because it is unclear as what specific biological function or enzymatic activity is possessed by the recited 'derivatives thereof.'" (*Id.*)

The Examiner also asserted that in claims 14, 37, 60, and 83 "part 'b)' of each of the claims renders the claims vague and indefinite because the specific amino acid sequence of the biotin synthase which is to be encoded by the recited polynucleotide of part a) is not known and not recited." (*Id.* at 3.)

The Examiner further asserted "[i]n each of claims 14, 37, 60, and 83, part 'c)' of each of the claims renders the claims vague and indefinite because the specific 'stringent hybridization conditions' are not known, not recited, and not specifically defined by the specification." (*Id.*)

The Examiner further asserted that in claims 15, 38, 61, and 84 part b), is vague and indefinite "because the specific amino acid sequence of the biotin synthase which is to be encoded by the recited polynucleotide of part a) is not known and not recited" (*Id.*).

The Examiner suggested "[a]mending the claim to recite a 'polynucleotide encoding the polypeptide of SEQ ID NO: 8.'" (*Id.*)

With a view towards furthering prosecution, claims 13, 15, 36, 38, 59, 61, 82, and 84 have been cancelled without prejudice. Claims 14, 37, 60, and 83 have been amended to recite a specific sequence in part (b) and to further clarify the recitation of "stringent hybridizing conditions." Accordingly, it is respectfully submitted that the rejection is rendered moot and should be withdrawn.

§112, First Paragraph Rejections

1. Written Description

Claims 13, 36, 59, and 82 were rejected under 35 U.S.C. §112, first paragraph. (Paper No. 20041117 at 4). In making the rejection, the Examiner asserted that "[c]laims 13, 36, 59, and 82 are a [sic] genus claims that is [sic] directed toward any DNA molecule comprising any polynucleotide encoding a polypeptide of SEQ ID NO: 8 or any functional derivative of a polypeptide of SEQ ID NO: 8, where the said functional derivative is any polypeptide of any amino acid sequence, structure, and biological function which can be made or derived from the polypeptide of SEQ ID NO: 8 ...." (*Id.*).

With a view towards furthering prosecution claims 13, 36, 59, and 82 have been cancelled without prejudice. Accordingly, it is respectfully submitted that the rejection is rendered moot and should be withdrawn.

2. Enablement

Claims 13, 14, 36, 37, 59, 60, 82, and 83 were rejected under 35 U.S.C. §112, first paragraph. (Paper No. 20041117 at 5). In making the rejection, the Examiner asserted that "[t]he nature and breadth of claims 13, 36, 59, and 82 encompass any DNA molecule comprising any polynucleotide encoding a polypeptide

of SEQ ID NO: 8 or any functional derivative of a polypeptide of SEQ ID NO: 8, where the said functional derivative is any polypeptide of any amino acid sequence, structure, and biological function which can be made or derived from the polypeptide of SEQ ID NO: 8, and where the amino acid sequence of the derivative has amino acid insertions, deletions, substitutions, and combinations thereof in SEQ ID NO: 8 as defined by the specification (see p. 7, lines 5-8)." (*Id.*)

The Examiner further asserted "[t]he nature and breadth of claims 14, 37, 60, and 83 encompass any DNA molecule comprising any polynucleotide encoding a biotin synthase, where the said any polynucleotide encoding a biotin synthase hybridizes under any stringent hybridization conditions to SEQ ID NO: 7." (*Id.*)

The Examiner acknowledged, however, that the specification is "enabling for an isolated DNA molecule comprising a polynucleotide which encodes the polypeptide of SEQ ID NO: 8." (*Id.*).

With a view towards furthering prosecution, claims 13, 36, 59, and 82 have been cancelled without prejudice. Claims 14, 37, 60, and 83 have been rewritten as independent claims and amended to remove the recitation of "functional derivatives." Claims 14, 37, 60, and 83 have also been amended to further clarify the recitation of "stringent hybridizing conditions." Accordingly, it is respectfully submitted that the rejection is rendered moot and should be withdrawn.

§102(b) Rejection

Claims 13, 14, 36, 37, 59, 60, 82, and 83 were rejected under 35 U.S.C. §102(b) as anticipated by Ohsawa *et al.*, *Cloning of the biotin synthetase gene from*

Bacillus sphaericus and expression in Escherichia coli and Bacilli., Gene. 1989; 80:39-48; and Accession Number M27867 ("Ohsawa"). (Paper No. 20041117 at 8).

In making the rejection, the Examiner asserted that "because the '996 bp polynucleotide (Accession M27-867) encoding biotin synthase ... is expected to hybridize to SEQ ID NO.: 7, the teachings of Ohsawa ... anticipate the invention of claims 14, 37, 60, and 83." (*Id.*). The Examiner also asserted that "the said polynucleotide (Accession M27867) falls within the scope of the polynucleotide which encodes functional derivatives of the polypeptide of SEQ ID NO.: 8 ... Ohsawa ... anticipate[s]... claims 13, 36, 59, and 82." (*Id.* at 9).

With a view towards furthering prosecution, claims 13, 36, 59, and 82 have been cancelled without prejudice. Claims 14, 37, 60, and 83 have been rewritten as independent claims and amended to remove the recitation of "functional derivatives". Claims 14, 37, 60, and 83 have also been amended to further clarify the recitation of "stringent hybridizing conditions." Accordingly, it is respectfully submitted that the rejection is rendered moot and should be withdrawn.

For the foregoing reasons, favorable action on the merits, including entry of the amendments, withdrawal of the rejections, and allowance of all the claims, respectfully are requested. If the Examiner has any questions regarding this paper, please contact the undersigned attorney.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box. 1450 Alexandria, VA 22313-1450, on April 4, 2005.

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